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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,016

02/26/2004

Tomoaki Hoshino

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12/15/2006

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,016

Applicant(s)

HOSHINO, TOMOAKI

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24 and 32-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24 and 32-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 25 October 2006 is acknowledged and entered.
Following the amendment, claim 24 is amended, and the new claims 32-50 are added.

Currently, claims 24 and 32-50 are pending.

Upon reviewing the new claims, second restriction requirement is warranted.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 24, 32-39 and 40 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is a monoclonal antibody for IL-18, classified in class 424, subclass 141.1.
- II. Claims 24, 32-39 and 40 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is a monoclonal antibody for IL-18 *receptor*, classified in class 424, subclass 141.1.
- III. Claims 24, 32-39, 41, and 49 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is a substance inhibiting conversion of a precursor of IL-18 into an activated one, classified in classification depending upon the chemical entity of the substance.
- IV. Claims 24, 32-39, 42, and 49 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is an inhibitor of cysteine protease, classified in class 424, subclass 94.1.
- V. Claims 24, 32-39, 43, and 49 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is an IL-1 β converting enzyme inhibitor, classification depending upon the chemical entity of the inhibitor.
- VI. Claims 24, 32-39, 44, and 49 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-18 inhibitor is an IL-18BP, classified in class 514, subclass 2.

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- VII. Claims 24, 32-39, 45 in part, 46, and 50 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-2 inhibitor is a monoclonal antibody for IL-2, classified in class 424, subclass 141.1.
- VIII. Claims 24, 32-39, 45 in part, 48, and 50 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-2 inhibitor is a monoclonal antibody for IL-2 *receptor*, classified in class 424, subclass 141.1.
- IX. Claims 24, 32-39, 47, and 50 in part, drawn to a composition comprising at least one of an IL-18 inhibitor and/or an IL-2 inhibitor, wherein the IL-2 inhibitor is an IL-2-diphtheria toxin conjugate, classified in class 424, subclass 183.1.

The inventions are distinct, each from the other because:

Inventions I-IX are drawn to independent and unrelated products, which are physically and functionally distinct chemical entities, and share neither structure nor function. Also, each is not required for the manufacture of another. Thus, non-coextensive searches are required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

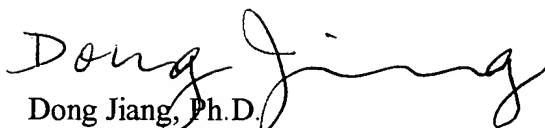
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Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dong Jiang, Ph.D.
Patent Examiner

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12/8/06